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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,570	09/27/2001	Toshiya Kai	NPR-085	8923
20374	7590	05/29/2003		
KUBOVCIK & KUBOVCIK SUITE 710 900 17TH STREET NW WASHINGTON, DC 20006			EXAMINER	
			GOLLAMUDI, SHARMILA S	
		ART UNIT	PAPER NUMBER	
		1616		

DATE MAILED: 05/29/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/963,570	KAI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 21 March 2003.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,4,6-11 and 13-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1, 4, 6-11, and 13-22 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

Receipt for Request for Continued Examination received on March 21, 2003 is acknowledged. Claims 1, 4, 6-11, and 13-22 are included in the prosecution of this application. Claim 12 stands cancelled.

### ***Double Patenting***

**Rejection of claims 1, 4, 6-7, and 10-12 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 and 7 of US patent 6,464,977 is withdrawn with the filing of the Terminal Disclaimer in Paper No. 8.**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 1, 6-7, and 10-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Claim 1 has been amended to recite "up to 50% by weight of sodium chloride," which renders the claims indefinite and vague. It is unclear whether the limitation refers to the sodium chloride cores or the limitation is part of the Markush group reciting electrolytes for the coating layer. Further clarification is requested.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1, 4, 6-11, and 19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Aoyama et al (5540842).**

Aoyama discloses a dialysis powder. The powder contains 78% NaCl particles coated with instant electrolytes (Mg, K, CaCl) (abstract and examples). Acetic acid is added to the particles (column 5, lines 15-19). Glucose (optional) is added separately and Aoyama teaches examples in which glucose is added (column 5, lines 20-23 and example 3). Aoyama discloses the use of sodium carbonate with the powder mixture. Particle size is taught in Table 9.

\*Note it is the examiner's position that a sugar particle coated with the same sugar is in essence the core sugar particle; therefore Aoyama's glucose reads on instant claims. In regards to the product-by-process claims determination of patentability is based on the product itself and the patentability of a product does not depend on its method of production. If the product is same or obvious to that of the prior art as seen in instant case, then the claim is unpatentable even though it was made by a different process.

### ***Response to Arguments***

Applicant argues that the glucose added in Aoyama is added during the preparation of component A and is deposited on the NaCl particles along with the other electrolyte compounds. It is argued that in the present invention, the glucose is used as a core particle and used for forming other particles.

Applicant's arguments have been fully considered but they are not persuasive. The examiner points to column 5, lines 2-23 wherein Aoyama discloses the incorporation of glucose after the coating layer is formed and during the incorporation of the acetic acid. Secondly, it is pointed out that all three components, the solid coated particles, the sugar, and the acid, are combined to form one product; therefore when the three components are mixed all the components will interact. Lastly, it is pointed out that the claims recites a product for dialysis and irrespective of how the composition is made, the prior art contains the all the components of the instant invention.

**Claims 1, 4, 6-11, and 13-22 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0399918.**

EP teaches a powder dialysis preparation containing two compositions. The first composition contains 2188.7 parts sodium chloride particles with a coating layer of 35.6 parts magnesium chloride hexahydrate, 77.2 parts calcium monohydrate monohydrate, 215.2 parts sodium acetate trihydrate, and acetic acid with instant particle sizes (examples 1-3). Examples and claims show that glucose particles are added to the electrolyte composition. See page 4 and 8-9. In example 2, sodium chloride is sprayed with an aqueous solution of the instant electrolytes are sprayed. The second composition contains glucose and sodium hydrogen bicarbonate with instant particle size (example 3).

In regards to the product-by-process claims see MPEP 2113.

***Response to Arguments***

Applicant argues that the obviousness rejection is improper. Further, applicant argues that the essential difference in EP is that the sugar is mixed with sodium hydrogen carbonate and dried, thus the particle is not covered with glucose. Lastly it is argued that there is no motive to coat glucose with glucose.

Applicant's arguments have been fully considered but they are not persuasive. The argument regarding the motivation in the obviousness rejection is moot because after further review of the prior art, EP is considered to anticipate the instant invention. In example 2, sodium chloride is sprayed with an aqueous solution of the instant electrolytes are sprayed.

In regards to the argument pertaining to the second composition, the examiner points out that the claim recites "core particles comprising particles of sugar, the core particles being covered with a coating layer comprising said sugar or different sugar." Once again the examiner points out that if a particle is coated with the same substance, then it is not different; therefore, glucose coated with glucose is glucose and EP teaches glucose in the second composition. The claim language does not exclude additional ingredients or coating layers on the sugar particles. The particle size of the glucose as taught in the examples and page 7, lines 24-25 is that of the instant particles size recited in the dependent claims.

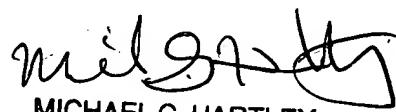
#### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG  
  
May 23, 2003

  
MICHAEL G. HARTLEY  
PRIMARY EXAMINER